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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,265	11/04/2003	Brenda F. Baker	ISIS-5300	7033

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WOODCOCK WASHBURN LLP  
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PHILADELPHIA, PA 19103

EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/701,265

Applicant(s)

BAKER ET AL.

Examiner

J. D. Schultz, Ph.D.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-112, drawn to compositions comprising chimeric oligomers containing regions of self-complementarity, classified in class 536, subclass 24.5.
- II. Claims 113-118, drawn to methods of modulating the expression of target nucleic acids comprising contacting cells with compositions comprising chimeric oligomers containing regions of self-complementarity, or to methods of treatment comprising the administration of same, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compositions can be used in assays designed to test the efficacy of specific configurations of nucleotide modifications on RNase H. or dicer mediated cleavage. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

### *Species*

This application contains claims directed to the following patentably distinct species of modification configurations: gapmers, inverted gapmers, 3'-hemimers, 5'-hemimers and blockmers. The species are independent or distinct and are directed to related compounds. The related species are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Election of a single configuration as discussed above requires the further election of a single patentably distinct species of first type of sugar substituent selected from F, amino, trifluoroalkyl, trifluoroalkoxy, azido, aminooxy, alkyl, alkenyl, alkynyl, O-, S-, or N(R\*)-alkyl; O-, S-, or N(R\*)-alkenyl, O-, S-, or N(R\*)-alkynyl, O-, S- or N-aryl, O-, S-, or N(R\*)-aralkyl, or specific configuration of PNA/RNA, or a single 2' sugar substituent from the formula -X-Y, wherein: X is O, S, NR\*\*, or CR\* wherein each R\* is independently H or C<sub>1-6</sub> alkyl; and Y is substituted or unsubstituted C<sub>1-20</sub> alkyl, substituted or unsubstituted C<sub>2-20</sub> alkenyl, or substituted or unsubstituted C<sub>6-20</sub> aryl.

Election of alkyl, alkenyl, alkynyl, aryl and aralkyl requires the further election of a single substituted or unsubstituted C<sub>1</sub> to C<sub>10</sub> alkyl, C<sub>2</sub> to C<sub>10</sub> alkenyl, C<sub>2</sub> to C<sub>10</sub> alkynyl, C<sub>5</sub>-C<sub>20</sub> aryl or C<sub>6</sub>-C<sub>20</sub> aralkyl.

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Election of substituted  $C_1$  to  $C_{10}$  alkyl,  $C_2$  to  $C_{10}$  alkenyl,  $C_2$  to  $C_{10}$  alkynyl,  $C_5$ - $C_{20}$  aryl or  $C_6$ - $C_{20}$  aralkyl requires the further election of a single substitution with alkoxy, thioalkoxy, phthalimido, halogen, amino, keto, carboxyl, nitro, nitroso, cyano, trifluoromethyl, trifluoromethoxy, imidazole, azido, hydrazino, aminooxy, isocyanato, sulfoxide, sulfone, disulfide, silyl, heterocycle, carbocycle, an intercalator, a reporter group, a conjugate, a polyamine, a polyamide, a polyalkylene glycol, or a polyether of the formula  $(-O\text{-alkyl})_m$ , where  $m$  is 1 to about 10; and  $R^*$  is hydrogen, or a protecting group. All species listed above are distinct and are directed to related compounds. The related species are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Election of a single modification configuration selected from the group consisting of gapmers, inverted gapmers, 3'-hemimers, 5'-hemimers and blockmers also requires the further election of a single first region comprising a single combination of nucleobase and linkage modifications selected from the group consisting of non-phosphorous linkages or nucleobases attached by phosphorous linkages via non-sugar tethering groups, or  $\alpha$ -nucleosides linked by charged or neutral 3'-5' phosphorous linkages, or  $\alpha$ -nucleosides linked by charged or neutral 2'-5' phosphorous linkages, or  $\alpha$ -nucleosides linked by non-phosphorous linkages, or 4'-thionucleosides linked by charged or neutral 3'-5' phosphorous linkages, or 4'-thionucleosides

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linked by charged or neutral 2'-5' phosphorous linkages, or 4'-thionucleosides linked by non-phosphorous linkages, or carbocyclic-nucleosides linked by charged or neutral 3'-5' phosphorous linkages, or carbocyclic-nucleosides linked by charged or neutral 2'-5' phosphorous linkages, or carbocyclic-nucleosides linked by non-phosphorous linkages, or  $\beta$ -nucleosides linked by charged or neutral 3'-5, linkages, or  $\beta$ -nucleosides linked by charged or neutral 2'-5' linkages, or  $\beta$ -nucleosides linked by non-phosphorous linkages.

Election of a single first region comprising a single combination of nucleobase and linkage modifications requires the further election of a single second region comprising a single combination of nucleobase modifications and linkage modifications selected from the group consisting of 2'-ribo- $\beta$ -nucleosides linked by charged 3'-5' phosphorous linkages, or wherein the second region comprises nucleobases linked by non-phosphorous linkages or nucleobases that are attached to phosphate linkages via a non-sugar tethering moiety. All species listed above are distinct and are directed to related compounds. The related species are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

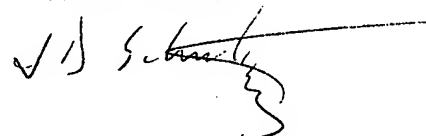
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'J. Schultz', is written over the printed name and title of the examiner.